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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,134	04/03/2001	David Wallach	WALLACH=16A	2547
1444	7590	03/04/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/824,134

**Applicant(s)**

WALLACH ET AL.

**Examiner**

MINH-TAM DAVIS

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/03/01</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant adds new claim 14, which is related to claims 1-7, 11 and is not new matter.

Accordingly, claims 1-7, 11, 14 are being examined.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE**

Rejection under 35 USC 112, first paragraph of claims 1-7, 11 pertaining to lack of enablement for a DNA sequence encoding an analog of the MORT-1 protein (SEQ ID NO:2) remains for reasons already of record in paper No.10. New claim 14 is rejected for the same reasons of record.

Applicant argues as follows:

The examiner's interpretation of claim 1(2) is incorrect where the examiner states that a substantial number of the hybridizing molecules encompassed by the claims would not share either structural or functional properties with polynucleotides that encode MORT-1 protein. The DNA sequence of claim 1(2) must encode an analog, which analog binds with the FAS-IC, and it is that sequence which must be capable of hybridizing to the CDNA encoding SEQ ID NO:2 under moderately stringent conditions. Thus, is not some other part of the DNA molecule that may hybridize to the CDNA encoding SEQ ID NO:2, but must be that sequence which encodes the analog that

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binds with the FAS-IC. If that that sequence both binds to FAS-IC and hybridizes to the cDNA encoding SEQ ID NO:2 under moderately stringent conditions, then it would be expected to share substantial sequence identity with SEQ ID NO:2. As explained in previous amendment, of February 24, 2003, it would be expected to require at least 75% homology. Any such sequence thus shares structural and functional (or physical) properties with polynucleotides that encode MORT-I protein.

Applicant's arguments set forth in paper of 12/03/03 have been considered but are not deemed to be persuasive for the following reasons:

The claims encompass variants, with unknown structure and function, wherein said variants share with the claimed polynucleotide sequence a polynucleotide fragment that encodes a fragment of SEQ ID NO:2 that binds to FAS-IC, and wherein said variants hybridize to the claimed polynucleotide via said polynucleotide fragment under moderately stringent conditions

Applicant has not taught how to make said variants such that they would have the function and properties of the claimed polynucleotide encoding SEQ ID NO:2.

One would not know how to make the claimed variants in view of a lack of adequate teaching in the specification, and in view of the unpredictability of protein chemistry, as taught by Burgess et al, Lazar et al, Tao et al and Gillies et al, all of record, and in view that said unpredictability applies as well to DNA sequences which encode proteins.

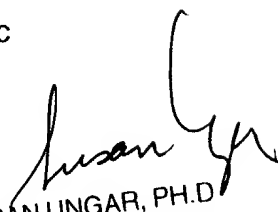
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

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MINH TAM DAVIS

March 01, 2004